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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,715	06/14/2005	Marie-Laure Fardeau	BJS-1721-94	1999
23117 7590 05/12/2011 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
KIM, TAEYOON				
ART UNIT		PAPER NUMBER		
1651				
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05/12/2011		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,715

Applicant(s)

FARDEAU ET AL.

Examiner

TAEYOON KIM

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2/18/2011 has been entered.

Claims 1-7 and 9-11 are cancelled, and claims 8 and 12 are pending. Claim 8 was indicated allowable. Claim 12 has been considered on the merit. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim is directed to an isolated bacterial strain of an *Exiguobacterium*

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lactigenes comprising a 16S rRNA sequence of SEQ ID NO:1 and a genomic DNA of the isolated bacterial strain is capable of hybridizing with at least 70% of the genomic DNA of the strain deposited under No. I-2962 with the Collection Nationale de Cultures de Microorganismes (strain 10C), and the isolated strain has properties of thermoresistant, saccharolytic, and/or amylolytic, producing L(+) lactate, growth properties at temperatures of 40-50°C, at pH 5.4-9.15 and a guanine and cytosine content being approximately 50 mol%.

The specification discloses only the deposited strain with deposit No. I-2962 (or strain 10C), which possesses the claimed functional properties and growth characteristics. The specification stated that the scope of the invention comprises the mutants of the strain conserving at least a 70% capacity for hybridization with the genomic DNA of the deposited strain (p. 3, lines 34-38). The specification does not provide any example of such mutants and/or variants having the claimed functional properties and growth characteristics (i.e. thermoresistant, saccharolytic, or amylolytic; producing L(+) lactate; having growth properties at temperatures of 40-50°C, at pH 5.4-9.15; and a guanine and cytosine content being approximately 50 mol%).

It is understood that one of ordinary skill in the art can identify bacteria having the sequences of SEQ ID NO:1 as a 16S rRNA based on the sequence and at least 70% of genomic DNA of the bacteria capable of hybridizing under any condition (e.g. either high or low stringent condition) to the genomic or plasmid DNA of the deposited strain (strain 10C; I-2962). However, it is construed that not all of those identified bacteria would have the claimed properties. Thus, a person of ordinary skill in the art would need to further identify those which have the claimed properties. However, the specification failed to

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provide any disclosure relating similarity of structure (sequences/domains) to conservation of function. The structural characteristics given to the isolated bacteria are SEQ ID NO:1 and at least 70% of genomic DNA of the isolated bacteria can hybridize (at any condition) to the genomic DNA of the deposited strain of No. I-2962. There is no disclosure of other information in the specification related to relate the structure to the functional properties of the claimed invention.

Without recognized correlation between structure and function, a person of ordinary skill in the art would not be able to identify without further testing which of those isolated bacteria possessing SEQ ID NO:1 and at least 70% of genomic DNA sequence being capable of hybridizing to the genomic DNA of deposited strain. In other words, merely at least 70% hybridization capability under unspecified condition would not allow one skilled in the art identifies a bacterial strain having the claimed functionality.

Therefore, those of ordinary skill in the art would not consider the Appellant to have been in possession of the claimed genus of isolated bacterium on the single species disclosed, and thus, it is concluded that the specification does not provide written description in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the entire scope of the claimed invention other than the deposited strain (I-2962).

M.P.E.P. §2163 states “To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d

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1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.”

M.P.E.P. § 2163 also recites, “An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention... one must define a compound by ‘whatever characteristics sufficiently distinguish it’. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.” and further, “The description needed to satisfy the requirements of 35 U.S.C. 112 “varies with the nature and scope of the invention at issue, and with the scientific and technological knowledge already in existence.” *Capon v. Eshhar*, 418 F.3d at 1357, 76 USPQ2d at 1084.< Patents and printed publications in the art should be relied upon to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for claims >present in the application when originally filed,< even if the specification discloses only a method of making the invention and the function of the invention. See, e.g., *In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992) (“One skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. Thus, an inventor is not required to describe every detail of his invention. An applicant’s disclosure obligation varies according to the art to which the invention pertains. Disclosing a microprocessor

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capable of performing certain functions is sufficient to satisfy the requirement of section 112, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out."). In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession."

Applicant is advised to delete the limitation directed to the properties of the isolated bacterial strain.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP § 2163.06 - § 2163.07(b) for a discussion of the relationship of new matter to 35 U.S.C. 112, first paragraph. New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the

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omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter.

The newly amended limitation of " the genomic DNA of said isolated bacterial strain is capable of hybridizing with at least 70% of the genomic DNA..." in claim 12 introduces a new matter to the application.

The specification of the instant application discloses:

"The bacterial strains of the invention are characterized in that they have a DNA sequence, at least part of which is capable of hybridizing with genomic or plasmid DNA of the strain ..." (p. 2, lines 33-36)

Based on the disclosure shown above, the original scope is directed to ANY DNA sequence of the isolated bacterial strain being capable of hybridizing with genomic DNA of the deposited strain. Upon the amendment, the scope of the limitation gets narrower, and thus, the newly added limitation is considered not to have adequate support from the originally filed application.

Conclusion

Claim 8 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651